

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

8

WHAT IS CLAIMED IS:

1. A method for delivering a medical device into the myocardium of a patient, comprising:

5 delivering a guidewire into the patient, the guidewire once delivered having a proximal end extending out of the patient and a distal end positioned adjacent the myocardium;

10 inserting the distal end of the guidewire into the myocardium;

anchoring the guidewire to the myocardium; and

15 advancing an introducer catheter carrying the medical device over the guidewire to deliver the device into the myocardium.

2. The method of Claim 1, wherein the guidewire is delivered percutaneously into the patient.

20 3. The method of Claim 2, wherein the distal end of the guidewire is advanced through a blockage in a coronary artery.

4. The method of Claim 2, wherein the distal end of the guidewire is advanced through a coronary vein.

25 5. The method of Claim 2, wherein the distal end of the guidewire is advanced into the left ventricle.

6. The method of Claim 1, further comprising advancing a delivery catheter into the patient prior to delivering the guidewire, the delivery catheter comprising a tubular body having a proximal end and a distal end and a lumen extending at least partially therethrough, until the distal end of the delivery catheter is positioned adjacent the myocardium.

30 7. The method of Claim 6, further comprising turning the distal end of the guidewire toward the myocardium prior to inserting the distal end of the guidewire, by:

actuating an anchoring member mounted on the distal end of the delivery catheter to secure the delivery catheter within the patient; and

35 actuating a steering member mounted on the distal end of the tubular body at a position distal to that of the anchoring member to turn the distal end

DRAFT DRAFT DRAFT

of the delivery catheter toward the myocardium; and

advancing the guidewire through the lumen in the delivery catheter and out the distal end of the delivery catheter.

8. The method of Claim 1, wherein the guidewire is a tip-deflecting wire, 5 and further comprising turning the distal end of the guidewire toward the myocardium prior to inserting the distal end of the guidewire by actuating the tip-deflecting wire.

9. The method of Claim 1, further comprising: 10 providing a passageway adjacent the myocardium having a proximal opening for receiving the distal end of the guidewire and a side port exit facing the myocardium;

wherein delivering the guidewire comprises advancing the distal end of the guidewire through the passageway toward the myocardium.

10. The method of Claim 9, wherein the passageway is provided through a lumen in a delivery catheter.

11. The method of Claim 9, wherein the passageway is provided through 15 an anchoring member mounted to a distal end of a delivery catheter.

12. The method of Claim 1, wherein anchoring the guidewire to the myocardium comprises providing at least one barb attached to the distal end of the guidewire, the barb having a shape that facilitates advancement of the guidewire distally through the myocardium but prevents retraction of the guidewire proximally. 20

13. The method of Claim 1, wherein inserting the distal end of the guidewire into the myocardium comprises advancing the guidewire from a coronary blood vessel until the distal end extends into the left ventricle.

14. The method of Claim 1, wherein anchoring the guidewire further 25 comprises expanding an anchoring member mounted on the distal end of the guidewire within the left ventricle.

15. The method of Claim 14, wherein the anchoring member is an inflatable balloon.

16. The method of Claim 1, wherein advancing the introducer catheter 30 carrying a medical device further comprises:

pulling proximally on the guidewire anchored to the myocardium; and pushing the introducer catheter over the guidewire into the myocardium.

17. A method for delivering a stent into the myocardium to bypass a blockage formed in a coronary artery, comprising:

5 creating a channel from a position proximal to the blockage in the coronary artery to a position distal to the blockage in the coronary artery;

advancing a guidewire through the channel until a distal end of the guidewire is adjacent the myocardium;

inserting the guidewire into the myocardium; and

10 advancing a stent over the guidewire into the myocardium.

18. The method of Claim 17 wherein the channel is a tunnel formed through the myocardium.

19. A method for creating a bypass through the myocardium of a patient to bypass a blockage formed in a coronary artery, comprising:

15 creating a first tunnel through the myocardium having a proximal end and a distal end, the proximal end opening into the coronary artery proximal to the blockage, and the distal end positioned within the myocardium;

creating a second tunnel through the myocardium, the second tunnel having a first branch extending from the distal end of the first tunnel and opening into the coronary artery at a position distal to the blockage, and a second branch extending from the distal end of the first channel and opening into the left ventricle; and

disposing a stent in the second tunnel to provide a myocardial passageway therethrough.

25 20. The method of Claim 19, further comprising closing off the first tunnel
at the distal end thereof.

21. The method of Claim 19, further comprising closing off the first tunnel at the proximal end thereof.

22. A delivery catheter, comprising:

30 an elongate tubular body having a proximal end and a distal end and a

RECEIVED
SEARCHED
INDEXED
SERIALIZED
FILED

lumen extending therethrough;
a first steering member mounted on the distal end of the tubular body;
and
a second steering member mounted on the distal end of the tubular body
5 at a position distal to that of the anchoring member.

23. The catheter of Claim 22, wherein the first steering member is an
expandable anchoring member which, when actuated, is sized to press against a wall
of the body lumen to secure the catheter within the lumen.

10 24. The catheter of Claim 23, wherein the second steering member is an
expandable member which, when actuated, cooperates with a wall of the body lumen
to turn the distal end of the catheter.

25. The catheter of Claim 22, wherein the anchoring member and steering
member are inflatable balloons.

15 26. The catheter of Claim 22, wherein the anchoring member is mounted
to one side of the tubular body and the steering member is mounted to an opposite
side of the tubular body.

27. A method for turning a distal end of a catheter within a body lumen, the
catheter comprising an elongate tubular body having a proximal end and a distal end,
the method comprising:

20 actuating an anchoring member mounted on the distal end of the tubular
body to secure the catheter against the body lumen; and

actuating a steering member mounted on the distal end of the tubular
body at a position distal to that of the anchoring member, wherein the steering
member when actuated cooperates with the body lumen to turn the distal end
25 of the catheter.

28. The method of Claim 27, wherein the anchoring member and the
steering member are inflatable balloons.

29. A method for delivering a medical device to a delivery site within a
patient comprising:

30 providing a delivery catheter having a proximal end and a distal end

- and a lumen extending therethrough into a body lumen of the patient; securing the delivery catheter within the body lumen; turning the distal end of the catheter by actuating a steering member mounted on the distal end of the catheter which pushes off against a wall of the body lumen; and
- 5 advancing the medical device through the lumen of the delivery catheter and out the distal end.
30. The method of Claim 29, wherein the steering member when actuated pushes off a wall of the body lumen to turn the distal end of the catheter.
- 10 31. The method of Claim 29, wherein securing the delivery catheter comprises actuating an anchoring member mounted on the distal end of the catheter against the wall of the body lumen.
32. The method of Claim 31, wherein actuating the anchoring member comprises inflating a balloon against the wall of the body lumen.
- 15 33. The method of Claim 29, wherein actuating the steering member comprises inflating a balloon against the wall of the body lumen.
34. A method for delivering a stent into the myocardium of a patient, comprising:
- 20 advancing a delivery catheter into the vasculature of the patient, the delivery catheter having a proximal end and a distal end and a lumen extending therethrough, until the distal end is adjacent the myocardium;
- actuating a pull wire extending from the distal end of the delivery catheter to turn the pull wire toward the myocardium;
- 25 advancing the pull wire from the distal end of the delivery catheter into the myocardium; and
- delivering the stent over the pull wire into the myocardium.
35. A method for delivering a stent into the myocardium of a patient, comprising:
- 30 advancing a delivery catheter into the vasculature of the patient, the catheter having a proximal end and a distal end and a lumen extending from

the proximal end to a side port near the distal end, until the side port faces the myocardium;

inserting a guidewire having a proximal end and a distal end into the lumen,

advancing the distal end of the guidewire through the lumen and out the side port;

puncturing the guidewire into the myocardium; and

delivering the stent over the guidewire into the myocardium.

5 advancing the distal end of the guidewire through the lumen and out the
side port;
puncturing the guidewire into the myocardium; and
delivering the stent over the guidewire into the myocardium.

36. The method of Claim 35, further comprising anchoring the delivery
catheter within the vasculature.

37. The method of Claim 35, wherein anchoring of the delivery catheter comprises expanding an anchoring member mounted to the distal end of the delivery catheter.

38. The method of Claim 37, wherein the anchoring member is an inflatable balloon.

39. The method of Claim 37, further comprising perfusing blood through at least one channel in the anchoring member.

40. A method for delivering a stent into the myocardium of a patient, comprising:

20 advancing a delivery catheter into the vasculature of a patient, the catheter having a proximal end and a distal end, until the distal end is adjacent the myocardium;

expanding an anchoring member mounted on the distal end of the catheter to secure the delivery catheter within the vasculature;

25 inserting a guidewire having a proximal end and a distal end through
a lumen in the expanded anchoring member, the lumen extending from a
proximal end of the anchoring member to a side port facing the myocardium,
so that the distal end of the guidewire exits through the side port;

puncturing the guidewire into the myocardium; and

advancing the stent over the guidewire into the myocardium.

41. The method of Claim 40, wherein expanding the anchoring member comprises inflating a balloon.
42. The method of Claim 40, further comprising perfusing blood through at least one channel in the expanded anchoring member.
- 5 43. A delivery catheter, comprising:
an elongate body having a proximal end and a distal end;
an expandable member mounted on the distal end of the tubular body, the expandable member having a proximal end and a distal end and an exterior surface; and
10 a guide lumen extending from the proximal end of the balloon to a side port on the exterior surface of the expandable member for directing a medical device therethrough
44. The delivery catheter of Claim 43, wherein the guide lumen extends through the elongate body from the side port to the proximal end of the elongate body.
- 15 45. The delivery catheter of Claim 43, wherein the guide lumen is separate from the elongate body.
46. The delivery catheter of Claim 43, wherein the guide lumen curves up to about 90 degrees.
- 20 47. The delivery catheter of Claim 43, wherein the expandable member is an inflatable balloon.
48. The delivery catheter of Claim 43, further comprising a perfusion channel to allow blood to flow therethrough.
49. The delivery catheter of Claim 48, wherein the perfusion channel extends through the expandable member.
- 25 50. A method for treating an aneurysm, comprising:
advancing a catheter having a proximal end and a distal end to the site of the aneurysm;
actuating an expandable member mounted on the distal end of the catheter to substantially enclose the aneurysm; and
30 inserting an embolic element through a lumen in the expandable

member into the aneurysm.

51. The method of Claim 50, wherein actuating the expandable member comprises inflating a balloon.

5 52. The method of Claim 50, further comprising perfusing blood through at least one channel in the expandable member.

53. The method of Claim 50, wherein the embolic element is a wire.

54. A method for delivering a medical device into a body tissue of a patient comprising:

10 inserting a guidewire having a proximal end and a distal end into the myocardium from a coronary blood vessel;

anchoring the guidewire to the body tissue;

pushing the medical device over the guidewire into the body tissue; and

15 pulling on the proximal end of the guidewire while advancing the medical device through the body tissue.

55. The method of Claim 54, wherein anchoring the guidewire comprises actuating an expandable member.

56. The method of Claim 55, wherein the expandable member is an inflatable balloon.

20 57. The method of Claim 54, further comprising providing at least one barb on the distal end of the guidewire to anchor the guidewire to the myocardium.

58. A delivery system for directing a medical treatment at least partially into the myocardium, comprising:

25 a guidewire having a proximal end and a distal end;

means for turning the distal end of the guidewire toward the myocardium;

means for anchoring the guidewire to the myocardium; and

30 a catheter carrying the medical treatment having a lumen extending therethrough for receiving the guidewire and advancing the catheter into the myocardium.

59. A method for delivering a stent into the myocardium of a patient to

bypass a blockage formed in a coronary artery, comprising:

- 5 advancing a catheter having a proximal end and a distal end and a lumen extending at least partially therethrough from the proximal end to a distal opening through the coronary artery of the patient until the distal opening is past the blockage;
- 10 turning the catheter so that the distal opening faces the myocardium;
- extending a wire having a proximal end and a distal end through the distal opening such that the distal end punctures into the myocardium;
- anchoring the distal end of the wire to the myocardium;
- 15 delivering a dilation catheter over the wire, the catheter carrying a dilation balloon on a distal end thereof, until the balloon is within the myocardium;
- inflating the dilation balloon to create an opening in the myocardium;
- deflating the dilation balloon and removing the dilation catheter from the wire;
- 15 delivering a stent introducer catheter over the wire, the stent introducer catheter carrying a stent on a distal end thereof, until the stent is located within the opening in the myocardium, and
- deploying the stent within the opening in the myocardium.

20 60. A method for delivering medical treatment into the myocardium of a patient, comprising:

- 25 delivering a tubular wire having a lumen extending therethrough into the patient, the wire once delivered having a proximal end extending out of the patient and a distal end positioned adjacent the myocardium;
- providing a means for turning the distal end of the wire towards the myocardium;
- inserting the distal end of the wire into the myocardium; and
- delivering the medical treatment through the lumen in the wire into the myocardium.

30 61. The method of Claim 60, wherein delivering medical treatment through

the lumen comprises providing drug fluid into the lumen at the proximal end.

62. The method of Claim 60, wherein the distal end of the wire further comprises at least one exit port.

5 63. The method of Claim 60, wherein the means for turning the distal end comprises delivering the wire through a delivery catheter.

64. The method of Claim 63, wherein the means for turning the distal end further comprises:

actuating an anchoring member mounted on a distal end of the delivery catheter to secure the delivery catheter within the patient; and

10 actuating a steering member mounted on the distal end of the tubular body at a position distal to that of the anchoring member to turn the distal end of the delivery catheter toward the myocardium.

65. The method of Claim 60, wherein the tubular wire is a pull wire, and the means for turning the distal end comprises actuating the pull wire.

15 66. The method of Claim 60, wherein the means for turning the distal end comprises:

providing a curved passageway adjacent the myocardium having a proximal opening for receiving the distal end of the tubular wire and a side port exit facing the myocardium; and

20 delivering the tubular wire through the curved passageway.

67. The method of Claim 66, wherein the passageway is provided through a lumen in a delivery catheter.

68. The method of Claim 66, wherein the passageway is provided through an anchoring member mounted to a distal end of a delivery catheter.

25